

Summary of Safety and Effectiveness

K955563

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Trade Name: BioloX ceramic heads for use with Foundation™ Forged, Textured and Porous Stems

Common Name: Ceramic femoral head

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented . prosthesis per 21 CFR 888.3353

Description: BioloX ceramic heads for use with Foundation™ Forged, Textured and Porous Stems that were cleared for commercial distribution in K952191, K935263 and K952297, respectively.

Intended Use: BioloX ceramic heads and Foundation™ Forged, Textured and Porous Stems are intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or femoral neck fracture, and revision arthroplasty where bone loss is minimal.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the BioloX heads used with SL-PLUS and SLR-PLUS Stems cleared for commercial distribution in K930963.

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